Polyethylene Glycol Versus Low Volume Solutions Prior to Colonoscopy

NCT02956057

3.1.2016

A head-to-head comparison of 4-L polyethylene glycol and low-volume solutions before colonoscopy. Methods This was a prospective, randomized, endoscopist-blinded, multicentre study. Outpatients referred to colonoscopy in the endoscopy departments of University Hospital in Brno, Prague and Bata Regional Hospital in Zlin were enrolled. Exclusion criteria were as follows: ileus or suspected bowel obstruction, gastroparesis, active bowel inflammation or bleeding, any presence of serious medical conditions, history of bowel surgery. Informed consent was obtained from all participants and study was approved by the ethics committee. The study was registered at https://clinicaltrials.gov (NCT02956057). The quality of bowel preparation was considered as the primary endpoint. Secondary endpoints included preparation tolerability, occurence of complaints during preparation and the impact of additional factors (product type, age, sex, constipation, ingested volume, BMI, diabetes) on the quality of the preparation and tolerability. The SING PEG group was prepared using PEG (Fortrans ™ plv. sol., Ipsen Pharma) in the afternoon before colonoscopy (4 sachets + 4L of water), split group (SPL\_PEG) used 3 sachets + 3 L water in the afternoon and 1 sachet + 1L water in the morning. SING\_SPMC group used 2 sachets of SPMC (Picoprep™ plv. sol., Ferring Pharmaceuticals ) in the afternoon before colonoscopy followed by 2 L of a water-based drink. SPL-SPMC group used SPMC in the afternoon (1 sachet + 1L of a drink) and the same dose in the morning before colonoscopy. SING-PEGA group used 2 sachets of PEGA(Moviprep <sup>™</sup> plv. sol, Norgine Ltd.) + 1 L of drink the afternoon before colonoscopy. SPL-PEGA prepared subjects ingested 1 sachet of PEGA + 1 L liquid in the afternoon and the same dose in the morning. Patients were instructed to be on a low-residue diet for three days before the colonoscopy. All the colonoscopy procedures were performed between 7:30 AM and 13:00 PM. The bowel preparation was assessed blindly using the Aronchick scale. Tolerability of the preparation was assessed using a 5point visual analogue scale (1-excellent, 5-very poor). The amount of ingested fluid during preparation, presence of nausea, vomiting, abdominal pain, bloating and incontinence during preparation and demographic data was recorded. The study authors had planned to enroll 174 patients in each group to provide 80% power to detect a 15% difference. The patients were randomized prospectively using a software, with 1:1 ratio between single and splitdose preparations for each laxative. Significance of differences was tested by the Kruskal-Wallis test with the Bonferroni correction. Association between categorical variables was assessed using the Fisher exact test. An multivariate logistic regression model was applied to measure the association of the baseline characteristics with quality or tolerability criteria. The level of statistical significance was 0.05 in all analyses.